SEP 17 2003

K030836
Page 1/2

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

| | |
|---|---|
| **Common/Usual Name:** | Topical Hemostat |
| **Product Trade Name:** | D-Stat Dry™ Hemostatic Bandage<br>D-Stat Radial™ Hemostatic Band |
| **Classification Name:** | Unclassified<br>Product Code MHW |
| **Manufacturer:** | Vascular Solutions, Inc.<br>2495 Xenium Lane North<br>Minneapolis, Minnesota 55441 |
| **Establishment Registration:** | 2134812 |
| **Contact:** | Deborah Jensen<br>VP Regulatory, Clinical and Quality Systems |
| **Performance Standards:** | No performance standards have been developed under section 514 for this device. |

**Device Description:**
The D-Stat Dry hemostatic bandage consists of the following components:

- Lyophilized pad consisting of thrombin, sodium carboxymethylcellulose and calcium chloride
- Adhesive bandage

The D-Stat Radial hemostatic band consists of the following components:

- Lyophilized pad consisting of thrombin, sodium carboxymethylcellulose and calcium chloride in a non-woven gauze
- Application device consisting of an adjustable retention strap, collar and attached gauze pad

The D-Stat Dry hemostatic bandage and D-Stat Radial hemostatic band achieves their principal intended action (hemostasis) by creating a physical barrier to blood flow with compression supplied by either the adhesive bandage or the retention band. The lyophilized components (thrombin, CMC, and calcium chloride) establish an environment, in which a natural blood clot can build and form a physical barrier to bleeding. The thrombin facilitates hemostasis by enhancing the surface-activated clotting cascade through enzymatic cleavage and conversion of fibrinogen to fibrin.

**Intended Use:**
The Vascular Solutions D-Stat—Dry Hemostatic Bandage and D-Stat Radial Hemostatic Band is intended for use under the direction of a healthcare professional for the local management and control of bleeding from vascular access sites and percutaneous catheters and tubes.

**Summary of Non-Clinical Testing:**
Testing conducted included assessments of the physical properties of the lyophilized pad, the ability of the lyophilized components to achieve its intended use (clot blood) and biocompatibility assessments. The results of this battery of tests confirmed the suitability of the D-Stat Dry Hemostatic Bandage and D-Stat Radial Hemostatic Band for its intended use.

**Summary of Clinical Testing:**
No clinical evaluations of this product for this use have been conducted.

**Predicate Devices:**
The intended use of the D-Stat Dry Hemostatic Bandage and D-Stat Radial Hemostatic Band is a subset of the intended use of the

- Vascular Solutions Inc., D-Stat Flowable Hemostat, K012293; product code MHW, unclassified.
- TZ Medical Inc., EZ Band; product code MHW class I
- Gambro Healthcare, Hospal Tipstop, K982818 (cleared for market distribution on October 21, 1998); product code KMF, Unclassified

**Conclusions:**
The D-Stat Dry Hemostatic Bandage and D-Stat Radial Hemostatic Band is substantially equivalent to Vascular Solutions Inc., D-Stat Flowable Hemostat, TZ Medical Inc., EZ Band, and the Gambro Healthcare Hospal Tipstop. The testing performed confirms that the D-Stat Dry Hemostatic Bandage and D-Stat Radial Hemostatic Band will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

Ms. Deborah Jensen
Vice President, Clinical and Quality Systems
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K030836
Trade/Device Name: Vascular Solutions D-Stat-Dry™ Hemostatic Bandage and D-Stat Radial™ Hemostatic Band
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 20, 2003
Received: June 23, 2003

Dear Ms. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number: K030836

Device Name: Vascular Solutions D-Stat—Dry™ Hemostatic Bandage and D-Stat Radial™ Hemostatic band

Indications for Use:

The Vascular Solutions D-Stat—Dry Hemostatic Bandage and D-Stat Radial Hemostatic Band is intended for use under the direction of a healthcare professional for the local management and control of bleeding from vascular access sites and percutaneous catheters and tubes.

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030836